DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

POLYMER TECHNOLOGY SYSTEMS, INC.
MARGO ENRIGHT
REGULATORY CONSULTANT
7736 ZIONSVILLE RD
INDIANAPOLIS IN 46268

December 22, 2016

Re: K140068
Trade/Device Name: CardioChek Plus Test System,
CardioChek Home Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, CHH, LBR, JGY
Dated: March 27, 2015
Received: March 30, 2015

Dear Ms. Margo Enright:

This letter corrects our substantially equivalent letter of May 22, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140068

Device Name
CardioChek Home Test System

Indications for Use *(Describe)*

The CardioChek Home Test System is a small portable analyzer and test strip system for self-testing by lay users. It is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140068

Device Name
CardioChek Plus Test System

Indications for Use *(Describe)*

The CardioChek Plus Test System is a small portable analyzer and test strip system intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5: 510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR 807.92.

April 24, 2015

Submitter Information/Facility Address:
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Margo Enright
Phone Number: 317-870-5610

email: menright@cardiochek.com

Trade Names: The CardioChek Plus and CardioChek Home Test Systems
This includes:

- CardioChek Plus professional analyzer
- CardioChek Home analyzer
- PTS Panels eGLU test strips/ CardioChek Home eGLU test strips
- PTS Panels Glucose test strips/ CardioChek Home Glucose test strips
- PTS Panels Lipid Panel test strips/ CardioChek Home Lipid Panel test strips

Classification Name(s): Cholesterol test system (21 CFR 862.1175), Class I, Exempt
Glucose test system (21 CFR 862.1345), Class II
Lipoprotein test system (21 CFR 862.1475), Class I, Exempt
Triglyceride test system (21 CFR 862.1705), Class I, Exempt

Panel: Clinical Chemistry 75

Product Codes:
CHH Cholesterol (total) test system
CGA Glucose test system
NBW Glucose test system
LBR Lipoprotein test system
JGY Triglyceride test system

Device Classification: Class II

Device Description:
The CardioChek Plus professional test system consists of the CardioChek Plus professional analyzer and analyte specific test strips and is intended for professional use. The CardioChek Plus professional analyzer is an in vitro diagnostic device consisting of both a reflectance photometer and amperometer. This device measures various analytes in blood once the blood is applied to dry phase test strips that are specifically designed for reflectance or amperometric (electrochemical) analysis.

The CardioChek Home test system consists of the CardioChek Home analyzer and analyte specific test strips. The CardioChek Home analyzer is an in vitro diagnostic device consisting of both a reflectance photometer and amperometer. This device measures various analytes in blood once the blood is applied to dry phase test strips that are specifically designed for reflectance or amperometric (electrochemical) analysis.

The CardioChek Plus professional and CardioChek Home test systems are a modification of the original device (cleared as BioScanner Plus, K014099) to include the following modifications:

- Wireless communications capability (professional system)
- Software solutions capability
- Printer connectivity capability
- MEMo chip appearance
- Battery type
- Multiple language software capability
- Wired PC Communication
- Analyzer dimensions

Intended Use:

The CardioChek Home Test System is a small portable analyzer and test strip system for self-testing by lay users. It is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The CardioChek Plus Test System is a small portable analyzer and test strip system intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The Glucose test strips for home use are intended for the quantitative determination of glucose in human whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Original 510(k):
K014099, BioScanner Plus System

Reason for Special 510(k):
Device Modifications
The CardioChek Plus professional and CardioChek Home test systems are a modification of the original device (cleared as BioScanner Plus, K014099) to include the following modifications:

- Wireless communications capability (professional system)
- Software solutions capability
- Printer connectivity capability
- MEMo chip appearance
- Battery type
- Multiple language software capability
- Wired PC Communication
- Analyzer dimensions

STATEMENT OF SUBSTANTIAL EQUIVALENCE;

The modified BioScanner Plus will be marketed to the professional market as the CardioChek Plus professional test system; the BioScanner Beyond Glucose test strips will be marketed as PTS Panels eGLU test strips, the BioScanner Glucose Test Strips will be marketed as PTS Panels Glucose test strips and the PTS Panels Lipid Panel test strips will be marketed under the PTS Panels Lipid Panel test strips name.). The CardioChek Plus System is substantially equivalent to the BioScanner Plus System (predicate).

The modified BioScanner Plus will be marketed to the self-testing market as the CardioChek Home test system; the BioScanner Beyond Glucose Test Strips will be marketed as CardioChek Home eGLU test strips, the BioScanner Glucose Test Strips will be marketed as CardioChek Home Glucose test strips and the PTS Panels Lipid Panel Test Strips will be marketed under the CardioChek Home Lipid Panel test strips name.). The CardioChek Home System is substantially equivalent to the BioScanner Plus System (predicate).

Predicate Device Information

Predicate
Name: BioScanner Plus System
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K014099

Name: Lipid Panel Test Strips
Device Company: Polymer Technology Systems, Inc. (PTS)
510(k) Number: K022898

Similarities and Differences (BioScanner Plus and CardioChek Plus)

Similarities

- Both systems employ both amperometric as well as reflectance photometry.
- Both systems provide results that correlate to reference methods.
- Both test systems use the same test strips.
- Both systems require a lot specific memory chip for result calculation, which are included in the same package with the test strips

Differences

- The software for the CardioChek Plus and CardioChek Home analyzers has multiple language options. The BioScanner Plus software was only in English.
- The CardioChek Plus and CardioChek Home analyzers provide:
  - Software solutions capability
  - Wired PC communication capability
  - Printer connectivity capability via a USB
  - Wireless communication capability (professional analyzer)
- The MEMo chip appearance is changed to make it more aesthetically pleasing. (The printed circuit board inside is the unmodified.)

Differences (continued)

- Analyzer outer case is larger.
- The modified analyzers use 4 AA batteries; the BioScanner Plus uses 2 AAA batteries.

Conclusion:

The CardioChek Plus and CardioChek Home test systems are as safe and effective and perform as well as our predicate device, the BioScanner Plus.